K061797

SEP - 1 2006

13. 510(K) SUMMARY

DIO Department, DSI, Inc.
117 Kyo-Dong, Yangsan-City,
Kyungnam-Do, 626-210, South Korea
Phone: 82-55-363-3401
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510(K) Summary

510(K) SUMMARY AND CERTIFICATION

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR & 807.93

13-1. Submitter	DIO Department, DSI, Inc. 117 Kyo-Dong, Yangsan-City, Kyungnam-Do, 626-210, South Korea Phone: 82-55-363-3401
13-2. US Agent / Contact Person	Dae Kyu Chang 13340 E. Firestone Blvd. Suite J Santa Fe Springs, CA 90670 Phone : 562-404-8466, Fax : 562-404-2757
13-3. Date Prepared	June 21, 2005
13-4. Device Name	SM® IMPLANT SYSTEMS
13-5. Classification Name	Endosseous Dental Implant System
13-6. Device Classification	Class II Dental Devices panel 21 CFR ξ 872.3640 Regulation Number: 872.3640
13-7. Predicate Devices	ANKYLOS® DENTAL IMPLANT SYSTEM (K012087)
13-8. Performance	Laboratory testing was conducted to determine device functionality and conformance to design input requirements.

13-9.Device Description

The SM Implant System is a root-form threaded dental implant made of Grade 3 and Grade 4 titanium. The implant is produced by machining process, followed by grit blasting and cleaning. It is available in diameters 3.8, 4.5, and 5.3 mm, and lengths from 8mm to 14 mm. It is placed via one or two stage surgery and the functional loading can be from immediate to delay.

13-10. Packing / Labeling / Product Information

In a clean room that is Class 10,000 or less, put the product into a capsule, and then put the capsule in a pet container, which is 45mm by 75mm, then sealed the pet container with PERFECSEAL CR27 1073B Coated Tyvek®. SM™ Implant Systems (SM™ Implant Fixtures, SM Protective Cap, and SM Implant System Surgery Tray) will be packaged.

13-11. Intended Use

The SM® Implant System is an endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on four splinted interforminal placed implants, and not indicated for single, unsplinted implants. Patients must be subject for dental treatment with endosseous implants.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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DIO Department DSI, Incorporated
C/O Mr. Dae Kyu Chang
President/Manager
Kodent, Incorporated
13340 East Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K061797
Trade/Device Name: SM Implant Systems
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: August 22, 2006
Received: August 28, 2006

Dear Mr. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K061797

Indication for Use

510(K) Number (if known): _____

Device Name: SM Implant Systems

Indications for Use:

The SM® Implant System is an endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on four splinted interforminal placed implants, and not indicated for single, unsplinted implants.

Susan Runner

n Sign-Off)
ion of Anesthesiology, General Hospital,
ion Control, Dental Devices

) Number: _____

Prescription Use X AND/OR _____ Over – The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)